REMARKS

The Official Action of January 8, 2003, and the prior art cited and relied upon therein have been carefully reviewed. The claims in the application are now claims 20-26, 32, 33, 38, 39, 42 and 43, with nonelected claims 11-19, 27-31, 35-37, 40 and 41 being withdrawn from consideration by the examiner, and these claims define patentable subject matter warranting their allowance. Accordingly, applicants respectfully request favorable reconsideration and allowance.

Acknowledgement by the PTO of the receipt of applicants' papers filed under Section 119 is noted.

Applicants re-traverse the Restriction Requirement which has been made final. Examiner has conceded that the standard to be applied is "unity-of-invention" per PCT Rules 13.1 and 13.2, not US restriction practice. With respect to this, claim 20, part of the elected subject matter, originally depended from and incorporated the subject matter of claim 35, part of non-elected Group II. Insofar as these two claims are concerned, from two separate groups, the common subject matter appears in claim 35, i.e. claim 35 defines the same special technical feature, which is not defeated by the prior art as discussed further below. Claims 22-25 also originally depended from claim 35, as did claims 32, 39 and 42.

Applicants therefore believe that all the groups relate to a single general inventive concept under PCT Rules 13.1 and 13.2, whereby the requirement should be withdrawn and plural groups examined on the merits.

The drawings are objected to by the Examiner, specifically the margins on Figure 4. A corrected drawing is enclosed herewith.

The specification is objected to by the Examiner. Specifically, the title is objected to and has been amended accordingly.

Claims 20 and 21 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter. This rejection is respectfully traversed.

The claims have been amended in accordance with Examiner's suggestion so that the base claim, claim 20, reads on an "isolated" antibody.

Claims 20-26, 32, 33, 38, 39, 42 and 43 have been rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the invention. This rejection is respectfully traversed.

Citing Vas-Cath, the Examiner states that because the limitations of claim 35 are so broad, it reads on a protein having any amino acid sequence. Therefore, the specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." Vas-Cath at page 1116.

Claims 20, 22, 24, 25, 32, 33, 42 and 43 have been amended to positively recite residues 1-231 of SEQ ID NO:2. Also, the support for the recitation of the stringency of the hybridization is found in the specification on pages 20-21. This rejection is therefore obviated by the amendments to the claims. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 20-26, 32, 33, 38, 39, 42 and 43 are rejected under 35 USC 112, first paragraph. The Examiner states that the specification does not provide enablement for an antibody that binds to any and all polypeptides or methods of using an antibody that binds to a protein comprising SEQ ID NO:2 or 4 to detect or diagnose any condition other than pancreatitis, citing the factors for undue experimentation from *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404. This rejection is respectfully traversed.

Claims 20, 22, 24, 25, 32, 33, 42 and 43 have been amended. Further, Applicants wish to point out that in the

present application, on page 4, second paragraph to page 7, first paragraph, descriptions are to be found as to how other kinds of serine proteases may be used for detecting or diagnosing Alzheimer's disease. Additionally, page 7, second paragraph to page 9, first paragraph describes other kinds of serine proteases used in the detection or diagnosis of cancer. Subsequent discussions on page 16, line 10, to page 17, line 3, reveal sites where the serine proteases of the present invention are expressed. Therefore, it can be presumed that one of ordinary skill in the art would be able to use serine proteases of the present invention both for detecting or diagnosing Alzheimer's disease and cancer.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 20-26, 32, 33, 38, 39, 42 and 43 have been rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regard as the invention. This rejection is respectfully traversed.

The Examiner states that claims 20-26, 32, 33, 38, 39, 42 and 43 are indefinite because they depend from claim 35, directed in part to a "modified derivative" of a protein. The definition of a "modified derivative" is found in the

instant specification on page 11, lines 4-7. Claims 20, 22, 24, 25, 32, 33, 42 and 43 have been amended in order to further clarify the scope of the invention.

The Examiner further states that claims 20-26, 32, 33, 38, 39, 42 and 43 are indefinite because they depend from claim 35, which displays inconsistencies in the labeling of its subparts and in antecedent basis issues. Claims 20, 22, 24, 25, 32, 33, 42 and 43 have been amended and address this.

Additionally, the Examiner asserts that claims 20-23 are indefinite in the recitation of "a fragment thereof". Claims 20 and 22 have been amended to address this issue.

Claim 22 is said to be indefinite for the recitation in lines 4-5. This issue is obviated by deletion of the recitation found to be indefinite by the examiner.

Claims 23-26, 38 and 39 are further said to be indefinite in being directed to a method of determining a protein or hBSSP5 in a specimen. Claims 22, 24, and 25 have been amended.

The Examiner states that claim 33 is indefinite in its being directed to a "pharmaceutical composition". This part of the rejection is obviated by the amendment to claim 33 to delete the recitation of "pharmaceutical."

The Examiner also states that claims 23, 42 and 43 are indefinite for reciting a use without steps delimiting how

to practice this use. While claim 42 has been amended, it is pointed out that claim 23 does indeed recite a positive step, namely "immunologically binding an antibody against the protein or a fragment thereof".

Claims 23, 42 and 43 are additionally rejected under 35 USC 101 due to the recitation of a use without setting forth any steps. As noted above, these claims have been amended, thereby obviating this part of the rejection.

The Examiner further states that claim 24 is indefinite in its recitation of "a labeled antibody". As discussed in the specification at pages 40, lines 20-25, through page 45, lines 1-3, which describes binding of an antibody with a labeled antibody, using either an enzymatic (e.g. alkaline phosphatase, horseradish peroxidase) or a fluorescent label, as is common in immunocytochemistry or immunohistochemistry. Therefore, Applicants assert that the use of the term "a labeled antibody" in claim 24 is not indefinite.

Claim 43 is said to be indefinite as it originally depended from a nonexistent claim 44. This claim has now been amended to correctly depend from claim 42.

Claims 20-26, 32, 33, 38, 39, 42 and 43 are additionally rejected under 35 USC 112, second paragraph, as being incomplete for omitting essential elements, *viz.*, those

recited in nonelected base claim 35. Said elements have been incorporated in the claim amendments to claims 20, 22, 24, 25, 32, 33, 42 and 43.

For the above reasons, reconsideration and withdrawal of the rejection are respectfully requested.

Claims 20, 21, 23, 24, 26 and 38 are rejected under 35 USC 102(b) as being anticipated by Carrere et al. The Examiner states that Carrere et al. teaches an antibody against chymotrypsinogen A, a method for determining a protein, further comprising a specimen that is a body fluid. This rejection is respectfully traversed.

This rejection is obviated by the amendment to claims 20 and 24. The claims do not recite an antibody against any protein, and to make this point even clearer, the amino acid sequence as defined by residue 1-231 of SEQ ID NO:2 is positively recited in the claims. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Claims 20, 21, 23, 25, 26 and 39 are rejected under 35 USC 102(b) as being anticipated by Geokas et al. This rejection is respectfully traversed.

The Examiner states that Geokas et al. teaches an antibody against human chymotrypsin II, as well as a method for determining a protein, further comprising a specimen that

is a body fluid. As claims 20 and 25 have been amended, this rejection is no longer apposite for the same reasons as in the 102(b) rejection over Carrere. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 20-23, 42 and 43 are rejected under 35 USC 102(b) as being anticipated by Chu et al. This rejection is respectfully traversed.

The Examiner states that Chu teaches an antibody against human PSA, as well as a process and methods. Again, because claims 20, 22, and 43 have been amended, this rejection is also obviated. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 20, 21, 23, 25, 26, 32, 33, 39 and 42 are rejected under 35 USC 102(b) as being anticipated by Iwaki et al. According to the Examiner, Iwaki et al. teach an antibody against human chymotrypsin II, as well as a method, including use of the antibody to detect pancreatitis. This rejection is respectfully traversed.

Again, as the amendments to the claims now make clear that the antibody in question is to a portion of the serine protease sequence, the 102(b) rejection is mooted. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Claims 33 and 42 are rejected under 35 USC 103(a) as being unpatentable over Lesi et al. in view of Carrere et al. The Examiner asserts that Lesi et al. teach a method for detecting a diagnostic marker in pancreatic disease, comprising a protein such as would be covered by broad unelected claim 35. This rejection is respectfully traversed.

Both claims 33 and 42 have been amended. However, upon examination of the Lesi reference, it is apparent that Lesi is only directed to the detection of chymotrypsin in fecal samples. Thus, the combination of Lesi and Carrere in no way suggests that antibodies to serine protein kinases might be of diagnostic use in pancreatitis. Thus, a *prima facie* case of obviousness cannot be sustained with these references.

It is thus submitted that the claims comply with 35 U.S.C. §112 and are free of the prior art. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

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